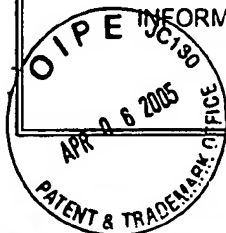


FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 4806-7	SERIAL NO. 10/775574
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		APPLICANT Barone, Jr. et al.	
		FILING DATE February 9, 2004	GROUP ART 1614



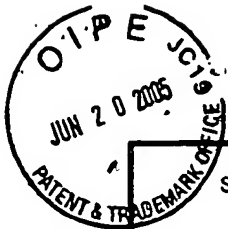
U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROP.
PL	A1.	5,985,860	11/16/99	Toppo	514	159	
↑	A2.	5,496,827	3/5/96	Patrick	514	310	
	A3.	5,451,407	9/19/95	Cornier et al.	424	448	
	A4.	5,318,960	6/7/94	Toppos	514	159	
	A5.	5,240,945	8/31/93	Warshaw	514	356	
	A6.	5,232,935	8/3/93	Colaset	514	356	
	A7.	2004/0102358	5/27/04	Scivioletto	514	1	
	A8.	2003/0059484 A1	3/3/2003	Bonte et al.	424	9.2	
↓	A9.	2002/0183297	12/502	Niazi	514	178	
PL	A10.	2002/0165429 A1	7/11/2002	Thompson	600	38	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
							YES	NO
	A11							
	A12							

EXAMINER <i>Patricia Smith</i>	DATE CONSIDERED 8/17/05
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT****Complete if Known**

Application Number	10/775574
Filing Date	February 9, 2004
First Named Inventor	Barone, Jr.
Art Unit	1614
Examiner Name	
Attorney Docket Number	5370-7

Sheet	1	of	4
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-kind Code ^{2 (if known)}	Publication Date	Name of Patentee of Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
PL	1.	US-5,217,997	June 8, 1993	5,217,997	
↑	2.	US-5,232,935	August 3, 1993	5,232,935	
	3.	US-5,240,945	August 31, 1993	5,240,945	
	4.	US-5,318,960	June 7, 1994	5,318,960	
	5.	US-5,428,070	June 27, 1995	5,428,070	
	6.	US-5,451,407	September 19, 1995	5,451,407	
	7.	US-5,496,827	March 5, 1996	5,496,827	
	8.	US-5,543,430	August 6, 1996	5,543,430	
	9.	US-5,595,753	January 21, 1997	5,595,753	
	10.	US-5,767,160	June 16, 1998	5,767,160	
	11.	US-5,891,459	April 6, 1999	5,891,459	
	12.	US-5,895,658	April 20, 1999	5,895,658	
	13.	US-5,922,332	July 13, 1999	5,922,332	
	14.	US-5,985,860	November 16, 1999	5,985,860	
	15.	US-6,007,824	December 28, 1999	6,007,824	
	16.	US-6,117,872	September 12, 2000	6,117,872	
	17.	US-6,207,713	March 27, 2001	6,207,713	
	18.	US-6,294,517	September 25, 2001	6,294,517	
	19.	US-6,323,211	November 27, 2001	6,323,211	
	20.	US-6,368,640	April 9, 2002	6,368,640	
	21.	US-6,428,791	August 6, 2002	6,428,791	
✓	22.	US-6,476,037	November 5, 2002	6,476,037	
PL	23.	US-6,544,563	April 8, 2003	6,544,563	
	24.	US-6,548,087	April 15, 2003	6,548,087	

Examiner Signature	<i>Edward J. Lee</i>	Date Considered	8/17/05
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				First Named Inventor	Barone, Jr.
				Art Unit	1614
Examiner Name					
Sheet	2	of	4	Attorney Docket Number	5370-7

PL	25.	US-6,548,841	October 1, 2002	6,458,841	
↑	26.	US-6,579,543	June 17, 2003	6,579,543	
↓	27.	US-6,646,006	November 11, 2003	6,646,006	
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↓	29.	US-2002-0183297	December 5, 2002	20020183297A1	
↓	30.	US-2003-0077296	April 24, 2003	20030077296A1	
PL	31.	US-2004-0102358	May 27, 2004	20040102358A1	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.†	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T*
		Country Code*	Number*	Kind Code* (if known)				
		PCT	-					
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			-					
			-					
			-					

OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)		
Examiner Initials*	Cite No.†	
PL	32.	Bumett A.L., Chang, A.G., Crone, J.K., Huang, P.L., Sezen, S.F., Noncholinergic Penile Erection in Mice lacking the gene for endothelial nitric oxide synthase. J. Andrology 23(1):92-97 (2002).
PL	33.	Cellek S, Moncada S, Nitrgic neurotransmission mediates the non-adrenergic non-cholinergic responses in the clitoral corpus cavernosum of the rabbit. Br. J. Pharmacol. 125(8):1627-9 (1998).
↓	34.	Christianson DW, Arginase: structure, mechanism, and physiological role in male and female sexual arousal. Acc. Chem. Res. 38(3):191-201 (2005).
↓ PL	35.	Elsner, P., Maibach, H.I. Cutaneous response to topical methyl nicotinate in human forearm and vulvar skin. J. Dermatol. Sci. 2(5):341-5 (1991).
PL	36.	Finnin, B., Transdermal Substance Delivery- What to Expect in the Near Future. Business Briefing: Pharmatech., pp. 182-183. (2003). <i>Office copy is illegible, need new readable copy</i>

Examiner Signature	<i>Patricia Zetta</i>	Date Considered	8/17/05
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Complete if Known	
				Application Number	10/775574
				Filing Date	February 9, 2004
				First Named Inventor	Barone, Jr.
				Art Unit	1614
				Examiner Name	
Sheet	3	of	4	Attorney Docket Number 5370-7	

PL	37.	Gonzalez-Cadavid NF, Rajfer J, Therapy of erectile dysfunction. Endocrine 23(2-3):167-76 (2004).
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✓	39.	Guy, RH, Maibach, H., Rapid radial transport of methyl nicotinate in the dermis, Archives Dermatol. Res. 273:91-95 (1982).
✓	40.	Irritants, Rubefacients and Vesicants, in Remington's Pharmaceutical Sciences 17th Edition, Mack Publishing Company, Eaton, Pennsylvania, p. 782, (1985).
✓	41.	Ito TY, Trant AS, Polan ML., A double-blind placebo-controlled study of ArginMax, a nutritional supplement for enhancement of female sexual function. J. Sex Marital Ther. 27(5):541-9 (2001).
✓	42.	Kim NN, Christianson DW, Traish AM, Role of arginase in the male and female sexual arousal response. J. Nutr. 134(10 Suppl):2873S-2879S; discussion 2895S (2004).
✓	43.	Klotz, T. Mathers, M.J. Braun, M., Bloch, W., Englemann, U. Effectiveness of oral L-arginine in first-line treatment of erectile dysfunction in a controlled crossover study. Urol. Int. 63(4):220-23 (1999).
✓	44.	Lebret, T, Herve JM, Gorny P, Worcel M, Botto H., Efficacy and safety of a novel combination of L-arginine glutamate and yohimbine hydrochloride: a new oral therapy for erectile dysfunction. Eur. Urol. 41(6):608-13; discussion 613 (2002).
✓	45.	McKay, D., Nutrients and botanicals for erectile dysfunction: examining the evidence. Altern. Med. Rev. 9(1):4-16 (2004).
✓	46.	Meston CM, Worcel M, The effects of yohimbine plus L-arginine glutamate on sexual arousal in postmenopausal women with sexual arousal disorder. Arch. Sex Behav. 31(4):323-32 (2002).
✓	47.	Moncada S., Higgs EA. Molecular mechanisms and therapeutic strategies related to nitric oxide. FASEB 9:1319-1330 (1995).
✓	48.	Muller, B., Kasper, M., Surber, C., Imanidis G., Permeation, metabolism and site of action concentration of nicotinic acid derivatives in human skin Correlation with topical pharmacological effect. Eu. J. Pharm. Sci. 20:181-95 (2003).
✓	49.	Park JK, Kim SZ, Kim SH, Kim YG, Cho KW, Renin angiotensin system of rabbit clitoral cavernosum: interaction with nitric oxide. J. Urol. 164(2):556-61 (2000).
✓	50.	Park JK, Kim JU, Lee SO, Hwang PH, Yi HK, Kim YG, Cho KW, Nitric oxide-cyclic GMP signaling pathway in the regulation of rabbit clitoral cavernosum tone. Exp. Biol. Med. 227(11):1022-30 (2002).
✓	51.	Sample of CONNECTION™ packaging including Ingredient list, enclosed herewith.
↓	52.	Sivamani RK, Stoeber B, Wu GC, Zhai H, Liepmann D, Maibach H., Clinical microneedle injection of methyl nicotinate: stratum comeum penetration. Skin Res. Technol. 11(2):152-6 (2005).
PL	53.	Stanislavov R, Nikolova V., Treatment of erectile dysfunction with pycnogenol and L-arginine. J. Sex Marital Ther. 29(3):207-13 (2003).

Examiner Signature	<i>Patricia Zeta</i>	Date Considered	8/17/05
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				First Named Inventor	Barone, Jr.
				Art Unit	1614
				Examiner Name	
Sheet	4	of	4	Attorney Docket Number	5370-7

PL	54.	Web page from the Better Business Bureau of Metropolitan New York, Inc., April 21, 2005.
PL	55.	Woolfson AD, Malcolm RK, Campbell K, Jones DS, Russell JA., Rheological, mechanical and membrane penetration properties of novel dual drug systems for percutaneous delivery. J Control Release. 3;67(2-3):395-408 (2000).

Examiner Signature		Date Considered	8/17/05
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